UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

09/27/07

DP BARCODE:	D335568
MRID:	469994-00, 471606-00, 469996-01, 469996-02, 471606-01, & 471606-02
SUBJECT:	ANTIMICROBIAL COPPER ALLOYS GROUP I^{+}
REG. NO. OR FILE SYMBOL:	82012-R
DOCUMENT TYPE:	Product Chemistry Review
Manufacturing-use [] OR	End-use Product [X]
INGREDIENTS (PC Codes)	Copper (022501)
CAS Number:	(7440-50-8)
TEST LAB:	None.
SUBMITTER:	Copper Development Association.
GUIDELINE:	830 Guidelines
COMMODITIES:	Formulation
REVIEWER:	Juan F. Negrón ORGANIZATION: AD
APPROVER:	Karen P. Hicks APPROVED DATE: 9/26/07
COMMENT:	

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

09/27/07

TO:	Marshall Swindell / Karen Leavy PM Team 33
FROM:	Juan F. Negrón, Chemist Product Science Branch, CT Team Antimicrobial Division (7510P)
THRU:	Karen P. Hicks, CT Team Leader Product Science Branch Antimicrobial Division (7510P)
THRU:	Michele E. Wingfield, Chief Product Science Branch Antimicrobial Division (7510P)
APPLICANT:	Copper Development Association
Action code:	A50
Due date:	11/21/07

Product Formulation
Active Ingredient(s)

	% by wt.
Copper	96.2

BACKGROUND:

The registrant, Copper Development Association, is submitting a new product for registration. The integrated end-use product, ANTIMICROBIAL COPPER ALLOYS GROUP I^{+}, reduces bacterial contamination.

FINDINGS:

1. The Product Chemistry Reviewer has received the following documents:
   - Letters dated 12/01/06, 06/07/07, & 08/09/07.
   - Labels dated 12/05/06, & 08/09/07 (pin punch).
   - Confidential Statements of Formula (CSFs), dated 11/29/06, & 06/06/07, for the basic formulation.
   - Preliminary analysis, dated 06/06/07.
   - Emails, dated 06/06/07, 06/12/07, & 08/09/07.
   - Request for wider certified limits, dated 08/09/07.
   - Study titled "Antimicrobial Copper Alloys Group I" Volume 2 of 19. MRID #469996-01.
   - Study titled "Antimicrobial Copper Alloys Group I – V Product Properties – Group B" Volume 3 of 19. MRID #469996-02.
   - Study titled "Antimicrobial Copper Alloys Group I Product Properties – Group B" Volume 1 of 2. MRID #471606-01.
   - Study titled "Antimicrobial Copper Alloys Group I Product Properties – Group A" Volume 2 of 2. Preliminary analysis, MRID #471606-02.

2. The CSF, dated 11/29/06, for the basic formulation is obsolete.

3. The label, dated 12/05/06, is obsolete.

4. The CSF, dated 06/06/07, for the basic formulation is revised.

5. The registrant is requesting a waiver for storage stability and corrosive characteristic studies for an unregistered product because of the stability of the metal.

CONCLUSION:

The CSF, dated 06/06/07, for the basic formulation is acceptable. The Agency granted a waiver for storage stability and corrosive characteristic studies. The Product Chemistry package is acceptable. As per last meeting between the Agency and the registrant, Mr. Kerry Leifer reviewed the data and assigned a PC code (as of 09/25/07) for all elements that were not cleared. These elements are acceptable for nonfood use in antimicrobial formulations only.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system []
- Are all TGAIs used registered? Yes [ ] No [ ]
- Integrated formulation system [X]
- If "ME-TOO," specify EPA Reg. No. of existing product: _____

b. Clearance of inerts for non-food or food use:
The product is cleared for food use under 40 CFR §§180.940 and 180.950.
Yes [] No [x]

c. Physical state of product: Solid

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.
Yes [X] No []

e. The NCs and CLs are acceptable. Yes [X] No [ ]

f. Active ingredient(s)

	NC (%)	LCL (%)	UCL (%)
Copper	96.2	92.3	100

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
Yes [ ] No [ ] Not applicable [X]
- Have all impurities of ≥ 0.1% in the product been identified?
Yes [ ] No [ ] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [] No [X]

b. The formula contains one of the following:

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [X] Not applicable []

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.
Yes [ ] No [ ] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.
Yes [X] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).
Yes [ ] No [x]

Table A:
Product Chemistry (830 Series, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A	469996-01
830.1600 Description of Materials	A	469996-01
830.1620 Production Process[2]	A	469996-01
830.1650 Formulation Process[3]	A	469996-01
830.1670 Formation of Impurities[4]	A	469996-01
830.1700 Preliminary Analysis[5]	A	471606-02
830.1750 Certified Limits[6]	See CSF dated 06/06/07	
830.1800 Analytical Method[7]	A	469996-01
830.1900 Submittal of Samples	[Samples are to be provided upon request.]	469996-01

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

---

[1]See Confidential Appendix A for additional information
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	NR		
830.6303 Physical State	A	Solid.	469996-02
830.6304 Odor	NR	Not required for end-use products.	
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NR	Not required for end-use products.	
830.6314 Oxidation/Reduction; Chemical Incompatibility	A	No adverse reaction was observed.	469996-02 & 471606-01
830.6315 Flammability/Flame Extension	A	Not flammable	469996-02 & 471606-01
830.6316 Explodability	A	Not explosive.	469996-02 & 471606-01
830.6317 Storage Stability	A	Requesting waiver since molecule is stable.	469996-02 & 471606-01
830.6319 Miscibility[1]	A	The product is a metal that cannot be mixture with any fluid.	469996-02 & 471606-01
830.6320 Corrosion Characteristics	A	The product is metal and no reaction will occur with the packaging material.	469996-02 & 471606-01
830.6321 Dielectric Breakdown Voltage	A	Not to be used around electrical equipment.	469996-02 & 471606-01
830.7000 pH[2]	A	Not miscible with water.	469996-02 & 471606-01
830.7050 UV/Visible Absorption	NR	Not required for end-use products.	
830.7100 Viscosity	A	Product is a metal.	469996-02 & 471606-01
830.7200 Melting Point/Melting Range	NR	Not required for end-use products.	
830.7220 Boiling Point/Boiling Range	NR	Not required for end-use products.	
830.7300 Density/Relative Density/Bulk Density	A	7.21 to 9.41 g/cm^3 .	469996-02 & 471606-01
830.7370 Dissociation Constants in Water	NR	Not required for end-use products.	
830.7550/830.7560/830.7570 Partition Coefficient	NR	Not required for end-use products.	
830.7840/830.7860 Water Solubility	NR	Not required for end-use products.	
830.7950 Vapor Pressure	NR	Not required for end-use products.	

Explanation: A=acceptable; N=not acceptable; NR= Not required; NA=technically not applicable; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

---

* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid
[2]If product is dispersible with water